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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,280	06/16/2006	Charles L. Sawyer	58086-232451 (2003-279-2)	2639

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EXAMINER	
AEDER, SEAN E	

ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/583,280	SAWYER ET AL.	
	Examiner	Art Unit	
	SEAN E. AEDER	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 5-24* is/are pending in the application.

4a) Of the above claim(s) *6,8 and 10-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,7,9 and 20-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/16/06; 11/1/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Election/Restriction

The response filed on 6/29/09 to the restriction requirement of 2/27/09 has been received. Without traverse, Applicant has elected Group I for examination.

Claims 1 and 5-24 are pending.

Claims 6, 8, and 10-19 are withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to a non-elected invention.

Claims 1, 5, 7, 9, and 20-24 are currently under consideration.

Inventorship

It is noted that the Reply of 6/26/09 requests that the first named inventor be corrected to "Charles L. Sawyers". At this time, this request cannot be granted. Please see the requirements set-forth at MPEP 1.48 for correcting inventorship. The request to correct the inventorship of this nonprovisional application is deficient because:

> An oath or declaration by each actual inventor or inventors listing the entire inventive entity has not been submitted.
>
> It lacks the required fee under 37 CFR 1.17(i).
>
> It lacks the written consent of any assignee of one of the originally named inventors.
>
> The request was not accompanied by the statement required under 37 CFR 1.48(b)(2).

Specification

The specification is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (paragraph 25). Applicant is required to delete all embedded hyperlinks and/or other form of browser-executable codes. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 7, 9, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 and dependent claims 7 and 9 are rejected because claim 5 recites the limitation "said normal selected cell". There is insufficient antecedent basis for this limitation in the claim.

Regarding claim 20, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 20-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a **NEW MATTER** rejection.

Claim 1 recites methods of examining physiological effects of a compound on a prostate cancer cell expressing exogenous wild-type androgen receptor polynucleotide wherein growth of said cell is "androgen-independent". Descriptions of methods of examining physiological effects of a compound on a prostate cancer cell expressing exogenous wild-type androgen receptor polynucleotide wherein growth of said cell is "androgen-independent" are not found in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the invention was filed, had possession of the claimed invention.

Claims 1 and 20-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the claims are inclusive of **a genus of compounds which (1) decrease androgen receptor DNA levels, androgen receptor mRNA levels, or androgen receptor protein levels and (2)**

inhibit the growth of hormone-refractory prostate cancer cells. The written description sets forth antisense constructs directed against androgen receptor expression which decrease androgen receptor DNA levels, androgen receptor mRNA levels, or androgen receptor protein levels. However, the specification does not disclose and the art does not teach the genus of compounds as broadly encompassed in the claims. It is noted that claims 20-23 recite possible ways such compounds would function; however, claims 20-23 and the specification do not disclose the genus.

In regards to the genus of compounds defined by function, without a correlation between structure and function, the claims do little more than define the compounds by function. That is not sufficient to satisfy the written description requirement. See Eli Lilly, 119 at1568 USPQ2d at 1406 ("definition by function…does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is").

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common to that genus that "constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus."

The inventions at issue in Lilly were DNA constructs per se, the holdings of that case is also applicable to claims such as those at issue here. Further, disclosure that does not adequately describe a product itself logically cannot adequately describe a method of using that product.

The court has since clarified that this standard applies to compounds other than cDNAs. See University of Rochester v. G.D. Searle & Co., Inc., F.3d, 2004 WL 260813, at *9 (Fed.Cir.Feb. 13, 2004). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genus. That is, the specification provides neither a representative number of compounds that encompass the genus nor does it provide a description of structural features that are common to the compounds. Since the disclosure fails to describe common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of antisense constructs directed against androgen receptor expression is insufficient to describe the genus. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus as broadly claimed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed

above, even though Applicant proposes methods of screening for possible members of the genus, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolation. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5, 7, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Burnstein et al (Molecular and Cellular Endocrinology, 1995, 115:177-186).

Claim 5 is drawn to a method comprising determining an abnormal level of mRNA in a selected cancer cell expressing an exogenous wild type polynucleotide that encodes a protein or polypeptide of interest as compared to the level of said mRNA that encodes a protein or polypeptide of interest in a normal cell, contacting a compound to be tested with said selected cancer cells, and examining one or more physiological characteristics of said treated cancer cell. Claim 7 is drawn to the method of claim 5 further comprising providing a mammalian cancer cell in which is the same as said selected cancer cell and which is not contacted with said compound to thereby provide a control cell, examining said one or more physiological characteristics of said control cancer cell, and comparing said one or more characteristics of said control cancer cell with said one or more characteristics of said treated cancer cell. Claim 9 is drawn to the method of claim 5 wherein said selected mammalian cell is selected from the group consisting of breast cancer cells, ovarian cancer cells and prostate cancer cells

Burnstein et al teaches to a method comprising determining an abnormal level of mRNA in a selected prostate cancer cell expressing an exogenous wild type polynucleotide that encodes a protein or polypeptide of interest (androgen receptor) as compared to the level of said mRNA that encodes a protein or polypeptide of interest in a normal cell, contacting a compound to be tested (androgen) with said selected cancer cells, and examining one or more physiological characteristics (down-regulation of androgen receptor mRNA) of said treated cancer cell (see right column on page 179, in particular). Burnstein further teaches a method comprising providing a mammalian cancer cell in which is the same as said selected cancer cell and which is not contacted

with said compound to thereby provide a control cell, examining said one or more physiological characteristics of said control cancer cell, and comparing said one or more characteristics of said control cancer cell with said one or more characteristics of said treated cancer cell (see Figure 1, in particular).

Claims 5, 7, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Cinar et al (Cancer Research, October 2001, 61: 7310-7317).

Cinar et al teaches to a method comprising determining an abnormal level of mRNA in a selected prostate cancer cell expressing an exogenous wild type polynucleotide that encodes a protein or polypeptide of interest (androgen receptor) as compared to the level of said mRNA that encodes a protein or polypeptide of interest in a normal cell, contacting a compound to be tested (R1881) with said selected cancer cells, and examining one or more physiological characteristics (cell growth) of said treated cancer cell (see Figure 3, in particular). Cinar further teaches a method comprising providing a mammalian cancer cell in which is the same as said selected cancer cell and which is not contacted with said compound to thereby provide a control cell, examining said one or more physiological characteristics of said control cancer cell, and comparing said one or more characteristics of said control cancer cell with said one or more characteristics of said treated cancer cell (see Figure 3, in particular).

Claims 5, 7, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Szelei et al (Endocrinology, 1997, 138(4): 1406-1412).

Szelei et al teaches to a method comprising determining an abnormal level of mRNA in a selected breast cancer cell expressing an exogenous wild type polynucleotide that encodes a protein or polypeptide of interest (androgen receptor) as compared to the level of said mRNA that encodes a protein or polypeptide of interest in a normal cell, contacting a compound to be tested (R1881) with said selected cancer cells, and examining one or more physiological characteristics (cell growth) of said treated cancer cell (see Figure 5, in particular). Szelei et al further teaches a method comprising providing a mammalian cancer cell in which is the same as said selected cancer cell and which is not contacted with said compound to thereby provide a control cell, examining said one or more physiological characteristics of said control cancer cell, and comparing said one or more characteristics of said control cancer cell with said one or more characteristics of said treated cancer cell (see Figure 5, in particular).

Claims 5, 7, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Raffo et al (Cancer Research, October 1995, 4438-4445).

Raffo et al teaches to a method comprising determining an abnormal level of mRNA in a selected prostate cancer cell expressing an exogenous wild type polynucleotide that encodes a protein or polypeptide of interest (bcl-2) as compared to the level of said mRNA that encodes a protein or polypeptide of interest in a normal cell, contacting a compound to be tested (FBS) with said selected cancer cells, and examining one or more physiological characteristics (cell growth) of said treated cancer cell (see Figure 4, in particular). Raffo et al further teaches a method comprising

providing a mammalian cancer cell in which is the same as said selected cancer cell and which is not contacted with said compound to thereby provide a control cell, examining said one or more physiological characteristics of said control cancer cell, and comparing said one or more characteristics of said control cancer cell with said one or more characteristics of said treated cancer cell (see Figure 4, in particular).

Summary

No claim is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN E. AEDER whose telephone number is (571)272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean E Aeder/
Primary Examiner, Art Unit 1642